



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,296	06/28/2004	Yuji Yamazaki	081356-0218	7715
22428	7590	10/12/2006		
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
			EXAMINER SKELDING, ZACHARY S	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/500,296

Applicant(s)

YAMAZAKI ET AL.

Examiner

Zachary Skelding

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 12, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 6, 8 and 10-25 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 2, 4, 6, 20-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>060914</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1644

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachary Skelding, Group Art Unit 1644.
2. Applicant's Amendment and Remarks, filed July 12, 2006, has been entered.
 - Claims 3, 5, 7 and 9 have been canceled.
 - Claims 1, 4, 6 and 8 have been amended.
 - Claims 20-25 have been added.
 - Claims 1, 2, 4, 6, 8 and 10-25 are pending.
3. Claims 1, 2, 4, 6 and 20-25 are under examination as they read on antibodies that bind SEQ ID NO: 1.
 - Claims 8 and 10-19 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being directed to a non-elected invention.
4. Upon further consideration, the previous species election associated with applicant's elected invention of Group I has been **VACATED**.

A supplemental species election is set forth below.

The Examiner apologizes to applicant for any inconvenience in this matter.

Species Election

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
6. Applicant is **required to elect** a species of anti-FGF-23 antibody from the following:
- (a) anti-FGF-23 antibodies that ***bind to amino acids 25-179 of SEQ ID NO: 1***, such as the antibodies produced by the hybridomas with accession numbers **FERM BP-7838** (aka the “2C3B antibody”) and **FERM BP-8268** (aka the “2C5L antibody”).

OR

- (b) anti-FGF-23 antibodies that ***bind to amino acids 180-194 of SEQ ID NO: 1***, such as “an antibody that recognizes an amino acid sequence that is present between the 180th and the 194th amino acid residues of SEQ ID NO: 1” (as recited in claim 1), including for example, the antibody produced by a hybridoma with accession number **FERM BP-7839** (aka the “3C1E antibody”);

OR

- (c) anti-FGF-23 antibodies that ***bind to amino acids 237-251 of SEQ ID NO: 1***, such as “an antibody that recognizes an amino acid sequence that is present between the 237th and the 251st amino acid residues of SEQ ID NO: 1” (as recited in claim 1), including for example, the antibody produced by a hybridoma with accession number **FERM BP-8268** (aka the “1D6A antibody”);

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features **for the following reasons:**

(1) Anti-FGF-23 antibodies that ***bind to amino acids 180-194 of SEQ ID NO: 1***, such as the antibody produced by a hybridoma with accession number **FERM BP-7839**, are disclosed in the prior art, for example, by Conklin (WO 01/49740), which discloses antibodies that bind amino acids 182-187 of FGF-23 (referred to as zFGF12 by Conklin)(see page 8, 1st and 2nd paragraphs).

(2) Since these antibodies bind specific, distinct sequences in FGF-23, these antibodies, in turn, have specific distinct structures, and they do not share a common structure that is disclosed to be essential for common utility.

Moreover, there is **not** an expectation, from the knowledge in the art, that each species could be substituted one for the other, with the expectation that the same intended result would be achieved. see M.P.E.P. § 1850 III(B).

Art Unit: 1644

For example, it was well known in the prior art that FGF-23 is subject to proteolytic cleavage around amino acid residue 180. Thus, one of ordinary skill in the art would appreciate that to detect the C-terminal fragment of cleaved FGF-23, antibodies that bind between amino acids 25-179 of SEQ ID NO: 1 could not be substituted for antibodies that bind, for example, to amino acids 237-251 of SEQ ID NO: 1.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1644

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
September 15, 2006

Phillip Gambel
PHILLIP GAMBEL, PH.D. JD
PRIMARY EXAMINER
TZ 1600
9/12/06